



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,511	10/06/2000	Raymond Andersen	P108281-0000	6795

7590 06/16/2005

Arent Fox Kintner Plotkin & Kahn
Suite 600
1050 Connecticut Avenue NW
Washington, DC 20036-5339

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,511

Applicant(s)

ANDERSEN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-25, 27, 29, 31-66 and 68-78 is/are pending in the application.
- 4a) Of the above claim(s) 24, 27, 29, 34, 59, 60, 62 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 31-33, 35-58, 63-66 and 68-73 is/are allowed.
- 6) ☒ Claim(s) 23, 61 and 75-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

158

Pursuant to the directives of the amendment filed 4/8/05, claims 22, 26, 28, 30, 67 have been cancelled, and the following claims amended: 23, 25, 27, 31, 34-38, 44, 47, 51, 53, 58, 60-66, 68-73, 75-78. Claims 23-25, 27, 29, 31-66, 68-78 are now pending. Claim 74 remains withdrawn from consideration pursuant to the original restriction. Claims 24, 27, 29, 34, 59, 60, 62 are withdrawn from consideration, since they do not encompass the elected specie. The following claims are examined in this Office action: 23, 25, 31-33, 35-58, 61, 63-66, 68-73, 75-78.

Applicants' arguments filed 4/8/05 have been considered and found persuasive in part. The rejection of claim 73 under 35 USC 112, first paragraph is withdrawn. For purposes of this Office action, the characterization of "allowable" is applied to each of the following claims: 25, 31-33, 35-58, 63-66, 68-73.



Claim 76 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 76, variable R_6 is undefined.



The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 61, 75 are rejected under 35 U.S.C. §102(a) as being anticipated by Johnson (WO 97/04004).

As indicated previously, Johnson discloses compound 26 (page 74). The disclosed compound (compound 26, page 74, Johnson) is encompassed by claim 23 when the substituent variables are as follows:

R1 = hydrogen;
R2 = hydrogen;
R3 = methyl;
R4 = methyl;
R5 = hydrogen;
R6 = hydrogen
R7 = methyl
R8 = hydrogen
Y = propylene substituted with isobutyl
Z = -O-CH₂-CH₃

Because of the term "having" in the claims, additional substituents can be added to the N- or C-terminus. Thus, the claims are anticipated.



Claims 61 and 75 are rejected under 35 U.S.C. §102(b) as being anticipated by Reetz (*Angew. Chem., Int. Ed. Engl.*, 31(12), 1626-9, 1992).

Reetz discloses compound 11 (page 1627, col 2). This compound would correspond to the substituent variables of the claims as follows, if not for one of the provisos:

R1 = hydrogen
R2 = tBoc
R3 = hydrogen
R4 = hydrogen
R5 = phenyl
R6 = hydrogen
R7 = methyl
R8 = hydrogen
Y = propylene substituted with isobutyl
Z = -O-CH₂-CH₃

As it happens, the cited claims exclude the possibility that R2 (or R1) can be *tert*-butyloxycarbonyl. However, the claims are drawn to a compound "having" the indicated structure. That is, the claim is not drawn to a compound "of" the formula; rather, the claim is drawn to a compound "having" the indicated formula. As such, the claim would permit additional substituents to be added to the N- or C-terminus. This ground of rejection then is not based on R₂ being tBoc; rather, it is based on R1 and R2 both representing hydrogen. Since the claimed peptide "has" the indicated structure, rather than consists of it, the claims would permit an additional substituent,

such as tBoc, to be bonded to the N-terminus. The same argument applies in the case of "Z".

Applicants have not traversed this ground of rejection, so the explanation provided in the previous Office action is maintained without further comment.



Claims 23 and 61 are rejected under 35 U.S.C. §102(b) as being anticipated by Falender (*Biocatalysis and Biotransformation* 13(2), 131-139, 1995).

Falender discloses the following compound on page 134 ("Ag" represents allylglycine):



The disclosed compound would be encompassed by the claims if the substituent variables could be as follows:

R1 = allylglycine;
R2 = hydrogen;
R3 = hydrogen;
R4 = hydrogen;
R5 = phenyl;
R6 = hydrogen;
R7 = benzyl;
R8 = hydrogen;
Y = butene;
Z = -O-CH₂-CH₃

Claim 23 excludes allylglycine as a possibility for R1; however, R1 and R2 can both be

hydrogen. This ground of rejection is justified because of the term "having" in the claim. This term permits additional substituents at the C- and/or N-terminus for the case of R1 and R2 both representing hydrogen.

Thus, the claims are anticipated.



Claims 23, 61, 75 are rejected under 35 U.S.C. §102(b) as being anticipated by Chang, L. L. (*Bioorganic & Medicinal Chemistry Letters* 2(10), 1207-12, 1992).

Chang discloses (page 1210) compound 25, which has the following structure ("Xaa" represents allylglycine):



The disclosed compound is encompassed by the instant claims when the substituent variables are as follows:

R1 = hydrogen;
R2 = hydrogen;
R3 = hydrogen;
R4 = hydrogen;
R5 = -CO-NH₂
R6 = hydrogen;
R7 = -CH₂-COOH
R8 = hydrogen;
Y = butene;
Z = -OH

When the substituent variables correspond as indicated above, the result is the following

tripeptide: Asn-Asp-Xaa. However, the claim is drawn to a peptide "having" the indicated structure, rather than consisting of it. Accordingly, additional amino acids can be added to the N-terminus. Applicants have not traversed this rejection, and so it is maintained without further comment.



Claim 75 is rejected under 35 U.S.C. §102(e) as being anticipated by Webber (USP 6,214,799).

Webber teaches various compounds falling within the scope of claim 1. For example, at col 18, line 20+ a compound is taught. This corresponds to applicants' substituent variables as follows (R^{20} is a variable created by the examiner):

Y = $-\text{CH}(R^{20})\text{CH}=\text{CH}-$ wherein R^{20} is the side chain of glutamine;
Z = $-\text{O}-\text{C}_2\text{H}_5$;
R8 = hydrogen;
R7 = benzyl;
R6 = hydrogen;
R3 = hydrogen;
R5 = hydrogen;
R4 = alkyl;
R1 = hydrogen;
R2 = a benzyl group that is "substituted" with oxo (resulting in a benzoyl group)

Claim 75 permits "Y" to be a "skeleton" that "contains" 1-10 carbon atoms. Since the term "contains" (or "containing") is open-ended language, the claim would permit additional atoms to be present in the "skeleton".

Thus, the claim is anticipated.



Claims 75, 77, 78 are rejected under 35 U.S.C. §102(e) as being anticipated by Eisenbach-Schwartz (USP 6,126,939).

Eisenbach-Schwartz discloses (col 3, line 56) the following tripeptide: Glu-Arg-Ala.

R7 = the side chain of arginine
R5 = -CH₂-COOH;
R1 = hydrogen
R2 = hydrogen
Y = ethyl;
Z = OH

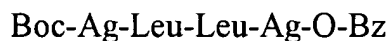
Unlike most of the other claims, claim 75 does not require "Y" to be an "unsaturated alkyl" group. Claim 75 permits variable R₉, together with the nitrogen atom to which it is bonded, to be a genetically encoded amino acid; that is, "Y" can be a "saturated moiety having a linear or branched...skeleton containing 1-10 carbon atoms", and containing also any other atoms (such as nitrogen, hydrogen, sulfur and oxygen) which may be of interest. As such, claim 75 encompasses most known tripeptides (even apart from the issue of the term "having"). Eisenbach-Schwartz is one of many references which disclose tripeptides falling within the scope of claim 75.

Applicants have not explained why how it is possible that this ground of rejection might be invalid; accordingly, it is maintained without further argument.



Claims 23, 61, 75 are rejected under 35 U.S.C. §102(b) as being anticipated by Grubbs (USP 5,811,515).

Grubbs discloses the following compound at col 14, lines 10-22 ("Ag" represents allylglycine; "Bz" represents benzyl):



The disclosed compound would be encompassed by claim 23 if the substituent variables could be as follows:

R1 = allylglycine;
R2 = tBoc;
R3 = hydrogen;
R4 = hydrogen;
R5 = isopropyl;
R6 = hydrogen;
R7 = CH₂-CH(Me)₂
R8 = hydrogen;
Y = butene;
Z = -O-CH₂-C₆H₅

Claim 23 does not permit R2 to be tBoc, or "Z" to be benzyloxy. However, the claim does permit R2 to be hydrogen, and "Z" to be -OH. At the same time, the claim is drawn to a peptide "having" the indicated structure. As such, additional functional groups can be added to the N-terminus and the C-terminus.

Thus, the claim is anticipated.



Claims 23, 61, 75 are rejected under 35 U.S.C. §102(b) as being anticipated by Baldwin, Jack E. (*J. Chem. Soc., Chem. Comm.* (16), 1280-1, 1986).

Baldwin discloses compounds 8, 1(b), and 1(c). The abbreviation "AA" represents *alpha*-aminoadipoyl (p. 1280, col 1, bottom of page).

Any of the three cited compounds anticipates the claims.



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 23 is rejected under 35 U.S.C. §103 as being unpatentable over Falender (*Biocatalysis and Biotransformation* 13(2), 131-139, 1995).

The teachings of Falender are indicated above. This ground of rejection is based on the possibility that at some point in the future, applicants will use the term "of", rather than

"having" to describe the claimed genus. Should this event come to pass, this ground of rejection will go into effect. This ground of rejection is predictated on the assertion that the compound in which R₇ is phenylethyl would have been obvious, i.e., that the enzymologist of ordinary skill would have expected, *a priori*, substantially identical activity for the two homologs. [*In re Shetty* (195 USPQ 753) and *In re Hass & Susie* (60 USPQ 544)]. Accordingly, excluding the compound in which variable R₇ is benzyl will not be effective to overcome this ground of rejection.

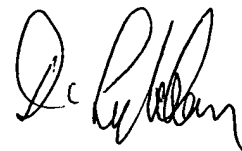
Thus, the claim is rendered obvious.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800